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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,116	08/06/2001	William F. McKay	4002-2803	9548

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EXAMINER

LE, EMILY M

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/923,116	MCKAY, WILLIAM F.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-47, 49, 52-56, 58-60, 62-64, 68, 73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-47, 49, 52-56, 58-60, 62-64, 68 and 73-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 05/19/2006 has been entered.

Status of Claims

2. Claims 1-42, 48, 50-51, 57, 61, 65-67 and 69-72 are cancelled. Claims 73-74 are added. Claims 43-47, 49, 52-56, 58-60, 62-64, 68 and 73-74 are pending and under examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 43-47, 49, 52-56, 58-59, 68 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 43-47, 49, 52-56, 58-59, 68 and 73 recites the transitional phrase "consisting essentially of".

MPEP § 2111.02 [R-3] provides, the transitional term "consisting essentially of"

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limits the scope of the claim to the specified step, and those that do not materially affect the basic and novel characteristics of the claimed invention.

In the instant, the Office recognizes that the claimed composition is limited to the specified ingredients; however, it is not readily apparent from the claims and the specification what or which other unspecified ingredients should be excluded to preserve the basic and novel characteristics of the claimed invention. This is particularly true because neither the specification nor the claims readily provide a clear teaching or clearly indicate the basic and novel characteristics that should be preserved with the claimed invention. Thus, in the absence of a clear indication from the specification and the claims of what the basic and novel characteristics actually are, the claims are rendered indefinitely because the metes and bounds of the claims are not readily be determined. For the purpose of examination, the phrase "consisting essentially of" will be treated as "comprising".

Claim 56 also recites "at least about". The cited recitation renders the claim indefinite. While the use of the terms "at least" and "about" does not render any claims indefinite for the relative metes and bounds of said terms can be determined; however, it is the combinational use of these terms, at least about, that renders claim 56 indefinite. In the instant, the relative metes and bounds encompassed by "at least about" cannot be determined. Thus, the claim is rejected under 112, 2nd paragraph for being indefinite.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 43, 45-47, 52, 60, 68 and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al.,¹ and as evidenced by McKay, W.²

The claims are directed toward an osteogenic composition comprising a stable and flexible device, wherein the device consists essentially of a resorbable sponge matrix formed of collagen and particulate biocompatible mineral embedded within the matrix, and an osteogenic factor. The claims require that the device comprises 1% to 3% by weight of collagen and 97% to 99% by weight of particulate biocompatible mineral. Independent claim 43 requires the collagen to be lyophilized. Claim 45, which depends on claim 43, limits the particulate biocompatible mineral to a synthetic ceramic, which is later limited to calcium phosphate by claim 46; which is further limited to biphasic calcium phosphate by claim 47. Claim 52, which depends on claim 43, requires the collagen to be telopeptide collagen. Claim 68, which depends on claim 43, requires the collagen to be fibrillar collagen.

Chu et al. teaches an osteogenic composition comprising a stable and flexible device, wherein the device comprise of a resorbable sponge matrix formed of collagen and particulate biocompatible mineral embedded within the matrix, and an osteogenic factor. [Examples 2-3, columns 12-13] The particulate biocompatible mineral that Chu et al. teaches is biphasic calcium phosphate, which is a calcium phosphate, which is also a

¹ Chu et al., U.S. Patent No. 4888366.

² McKay, W.F., U.S. Patent No. 5972368.

synthetic ceramic. The collagen that Chu et al. teaches is a telopeptide collagen and fibrillar collagen. [Lines 29-40, column 7; Line 64, column 12, respectively]

In the instant, a small difference exists between the percent by weight of collagen and particulate biocompatible mineral used Chu et al. and those instantly claimed. The percent by weight of collagen and particulate biocompatible mineral used by Chu et al. is 10% and 87.5%, respectively. And the percent by weight of collagen and particulate biocompatible mineral instantly claimed is 1% to 3% and 97% to 99%, respectively. However, MPEP § 2144.05 [R-3] (II) (A) sets forth that, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Specifically, MPEP § 2144.05 [R-3] (II) (A) provides the following: “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Thus, in view of the cited guidance provided in the MPEP, and in the absence of a disclosure citing that the claimed percent by weight of collagen and mineral is critical to the claimed invention, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use various percent by weight of collagen and mineral. The use of various percent by weight of collagen and

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mineral is also acknowledged by Chu et al. Chu et al. suggests the use of about 2-40%, preferably 5%-25% by weight of collagen, and 60%-98% by weight of mineral.

[Paragraph bridging columns 7-8] One of ordinary skill in the art at the time the invention was made would have been motivated to do so to determine the optimum or workable ranges. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the discovery or optimum or workable ranges is routinely practiced in the art.

It is noted that claims 43 and 45-47 require the collagen present be lyophilized collagen. In the instant, it is not readily apparent if the collagen used by Chu et al. is in lyophilized form. However, Chu et al. does recognize the use of the lyophilized form of collagen. [Lines 44-50, column 7] Chu further states that any non-reconstituted collagen preparation may be used. Hence, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use the lyophilized form of collagen. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to provide mineral/collagen carrier for the composition of Chu et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the lyophilized form of collagen is recognized in the art as an alternative equivalent to the collagen used by Chu et al.

Additionally, it is noted that while claims 73-74 is directed toward a product, the cited claims also recite the method in which the product is made. However, MPEP § 2113 [R-1] provides the following: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The

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patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). MPEP § 2113 [R-1] further provides that the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). In the instant, the process steps recited in the claims has been evaluated, however, no particular structural characteristic can be rendered from the process steps. The claimed composition remains to be an osteogenic composition, which is obvious over the teachings of the art cited herein.

It is further noted that the claims require the device to be three dimensionally stable and flexible. In the instant, it is noted that the Chu et al. is silent on the flexibility of the composition. However, in the absence data available for direct comparison, the final basis of compositional equality is based on the ingredients and the proportions of the ingredients used in the composition. Applicant claims the use of 1% to 3% by weight of collagen. Chu et al. teaches the use of 5% to 25% by weight of collagen. Applicant claims the use of 97% to 99% by weight of the particulate biocompatible mineral. Chu et al. teaches 60% to 98% by weight of the particulate biocompatible mineral. In both instances, the range that Chu et al. teaches encompasses the range that is instantly

claimed. Ergo, based on a comparative teaching between the instant disclosure and the disclosure of Chu et al. it is determined that the osteogenic compositions are the same. Any characteristics describing the claimed osteogenic composition would be inherent features in the osteogenic composition of Chu et al. because **the osteogenic compositions are indistinguishable**.

Furthermore, it is clearly evident from the teachings provided by Chu et al. that the composition of Chu et al. is flexible. Chu et al. teaches that compositions that contains a mixture of collagen and particulate biocompatible mineral cannot attain a modulus value that is much greater than 100 N/cm^2 , wherein compressive modulus measures the resiliency of a composition. In the instant, Chu et al. teaches a composition has a compressive modulus above 20 N/cm^2 , preferably $20\text{-}30 \text{ N/cm}^2$. [Paragraph bridging columns 8-9.] The compressive modulus value for the composition of Chu et al. is well within the 100 N/cm^2 threshold that is noted for such compositions. Thus, the composition of Chu et al. is resilient. Thus, the composition of Chu et al. is flexible.

Moreover, while Chu et al. is silent on the flexibility of the composition, however, it is well known in the art that the addition of collagen to a mineral based composition renders a composition elastic, as evidenced by McKay, W. McKay, W. teaches that the presence of collagen and mineral results in a composition that has an elasticity that is similar to bone. [Lines 7-12, column 18. In the instant, the composition of Chu et al. contains collagen. Hence, the composition of Chu et al. is resilient and has elastic activity. Thus, the composition of Chu et al. is flexible.

7. Claims 43-44 and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4888366, as applied to claim 43; in view of Geistlich et al.³

Claim 44, which depends on claim 43, limits the particulate biocompatible mineral to bone particles. Claim 56, which depends on claim 43, requires the particulate biocompatible mineral to have an average particle diameter of at least .5 mm. Claim 58, which depends on claim 43, requires the particulate biocompatible mineral to have an average particle diameter of about .5 mm to about 5 mm, which is later limited to about 1mm to about 3mm by claim 59.

The significance of Chu et al., as it pertains to claim 43, is provided above. The particulate biocompatible mineral that Chu et al. teaches is synthetic calcium phosphates. Chu et al. used the synthetic calcium phosphates instead of bone particles.

Geistlich et al. teaches the use of bone particles as the particulate biocompatible mineral. Geistlich et al. teaches that bone particles are highly biocompatible prosthetic bone replacement. Hence, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use bone particles as the particulate biocompatible mineral. One of ordinary skill in the art at the time the invention was made would have been motivated to do so for prosthetic bone replacement. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because bone particles and synthetic calcium phosphates are functional alternatives of the other.

³ Geistlich et al., U.S. Patent No. 5,573,771.

Additionally, it is not readily apparent what is the average particle size of the particulate biocompatible mineral used by Chu et al. Chu et al. simply teaches that any particle size can be used. [Lines 10-20, column 7.] In the instant, Geistlich et al. teaches that the following particle sizes can be used, 0.1 mm to 10 mm. [Line 67, column 4.] The range disclosed by Geistlich et al. encompasses the range claimed by Applicant. In the instant, the art recognizes the use of the claimed particle sizes. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use any particle sizes. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to discover the optimal or workable range. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the determination of an optimal or workable range is routinely practiced in the art.

8. Claims 43, 52-55, 60 and 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., as applied to claims 43 and 52; in view of McKay, W.

The significance of Chu et al., as it pertains to claims 43 and 52, is provided above.

Claim 53, which depends on claim 52, which depends on claim 43, limits the osteogenic factor to bone morphogenic protein (BMP), which is later limited to BMP-2 by claims 54-55. Claims 62-64 recite the same limitation as claims 53-55 with the exception that claims 62-64 recite a dependency to claim 60.

Chu et al. also teaches the use of bone morphogenic proteins as the osteogenic factor. [Lines 50-52, column 5.] While Chu et al. does not specifically teach BMP-2,

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however, Chu et al. teaches that any sources of osteogenic factors can be used. In the instant, McKay, W. teaches BMP-2. Hence, at the time the invention was made, BMP-2 is known in the art. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use any sources of osteogenic factor, including BMP-2. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to induce osteogenic growth. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because BMP-2 is a known osteogenic factor.

9. Claims 43 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., as applied to claim 43; in view of Michelson.⁴

Claim 49, which depends on claim 43, is directed toward an interbody spinal fusion device containing a load bearing member and the composition of claim 43.

The significance of Chu et al., as it pertains to claim 43, is provided above. Chu et al. does not teach an interbody spinal fusion device containing a load bearing member and the composition. As noted previously, Chu et al. teaches an osteogenic composition. However, Michelson teaches a spinal fusion implant device. Michelson suggests using the implant device to be filled with and hold any natural or artificial osteoconductive, osteoinductive or osteogenic material. (Line 20-27, column 3). Hence, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Michelson with Chu et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to facilitate

⁴ Michelson, U.S. Patent No. 5,785,710.

spinal osteogenic growth. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because Chu et al. teaches an osteogenic composition and Michelson teaches a spinal implant device for use with the osteogenic composition of Chu et al.

Response to Applicant's submission

10. In response to the prior art rejection(s) set forth in the previous office action, Applicant submits that Chu et al. away from a flexible osteogenic composition.

Applicant's complete submission has been considered, however, it is not found persuasive. The Office notes that the claims require the device to be three dimensionally stable and flexible. In the instant, it is noted that the Chu et al. is silent on the flexibility of the composition. However, in the absence data available for direct comparison, the final basis of compositional equality is based on the ingredients and the proportions of the ingredients used in the composition. Applicant claims the use of 1% to 3% by weight of collagen. Chu et al. teaches the use of 5% to 25% by weight of collagen. Applicant claims the use of 97% to 99% by weight of the particulate biocompatible mineral. Chu et al. teaches 60% to 98% by weight of the particulate biocompatible mineral. In both instances, the range that Chu et al. teaches encompasses the range that is instantly claimed. Ergo, based on a comparative teaching between the instant disclosure and the disclosure of Chu et al. it is determined that the osteogenic compositions are the same. Any characteristics describing the claimed osteogenic composition would be inherent features in the osteogenic composition of Chu et al. because **the osteogenic compositions are indistinguishable.**

Furthermore, it is clearly evident from the teachings provided by Chu et al. that the composition of Chu et al. is flexible. Chu et al. teaches that compositions that contains a mixture of collagen and particulate biocompatible mineral cannot attain a modulus value that is much greater than 100 N/cm^2 , wherein compressive modulus measures the resiliency of a composition. In the instant, Chu et al. teaches a composition has a compressive modulus above 20 N/cm^2 , preferably $20\text{-}30 \text{ N/cm}^2$. [Paragraph bridging columns 8-9.] The compressive modulus value for the composition of Chu et al. is well within the 100 N/cm^2 threshold that is noted for such compositions. Thus, the composition of Chu et al. is resilient. Thus, the composition of Chu et al. is flexible.

Moreover, while Chu et al. is silent on the flexibility of the composition, however, it is well known in the art that the addition of collagen to a mineral based composition renders a composition elastic, as evidenced by McKay, W. McKay, W. teaches that the presence of collagen and mineral results in a composition that has an elasticity that is similar to bone. [Lines 7-12, column 18. In the instant, the composition of Chu et al. contains collagen. Hence, the composition of Chu et al. is resilient and has elastic activity. Thus, the composition of Chu et al. is flexible.

Conclusion

11. No claims are allowed.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903.

The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Emily/Le 8/04/06
Patent Examiner
Art Unit 1648